UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2419** **No. 1:13-md-02419-RWZ**
THIS DOCUMENT RELATES TO: ALL ACTIONS	)	

MEMORANDUM IN SUPPORT OF U.S. FOOD AND DRUG ADMINISTRATION'S MOTION FOR PROTECTIVE ORDER AND IN OPPOSITION TO TENNESSEE CLINIC DEFENDANTS' MOTION TO COMPEL

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PRELIMINARY STATEMENT

By third-party subpoena dated March 5, 2015 (Subpoena), Tennessee Clinic Defendants directed the U.S. Food and Drug Administration (FDA) to produce one or more witnesses for deposition, along with six categories of documents. By letter dated March 20, 2015, FDA objected to the Subpoena. By motion dated April 14, 2015, Tennessee Clinic Defendants moved for an order directing FDA to comply with it.[1]

FDA and Tennessee Clinic Defendants have reached agreement on the production of documents under the Subpoena. The principal issue that exists with respect to the production of witnesses under the Subpoena is one of timing. That issue exists because of the pendency of *United States v. Cadden*, No. 1:14-cr-10363-RGS (D. Mass.), a criminal action arising from the same events from which this litigation allegedly arises. For the reasons set forth below, any production of witnesses under the Subpoena during the pendency of *Cadden* is likely to interfere with the prosecution of that action. Any such interference is especially problematic in view of the seriousness of the crimes with which the defendants in *Cadden* are charged. Because the public's interest in a just resolution of *Cadden* is and should be paramount, this Court should issue a protective order providing that FDA shall not be required to produce any witness for deposition under the Subpoena until 30 days after the completion of trial in *Cadden* or the entry of guilty pleas by all defendants in that action.[2]

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[1] "Tennessee Clinic Defendants" is the name by which the following defendants refer to themselves collectively in this litigation: Saint Thomas Outpatient Neurosurgical Center, L.L.C.; Howell Allen Clinic, P.C.; John Culclasure, M.D.; Debra Schamberg, R.N.; Vaughan Allen, M.D.; Specialty Surgery Center, Crossville, P.L.L.C.; Kenneth R. Lister, M.D.; Kenneth R. Lister, M.D., P.C.; and Donald E. Jones, M.D. ECF No. 1775 at 1; *see* n.2, *infra*.

[2] FDA also reserves the right to move for a protective order narrowing the scope of any deposition taken under the Subpoena or clarifying the scope of inquiry for any such deposition if agreement on those matters cannot be reached with Tennessee Clinic Defendants.

STATEMENT OF FACTS

A. This Litigation

This litigation is a multidistrict proceeding in which more than 680 tort actions under state law have been joined. *See* ECF No. 1811 at 3.[3] The actions joined in this litigation are alleged to "arise from the 2012 fungal meningitis outbreak caused by contaminated medication manufactured by the New England Compounding Center ('NECC')." ECF No. 1775 at 1. "The U.S. Centers for Disease Control and Prevention ('CDC') has reported that 751 patients in 20 states were diagnosed with a fungal infection after receiving injections of NECC's methylprednisolone acetate [MPA]." Ex. A ¶ 4.[4] "Of those 751 patients, the CDC reported that 64 patients in nine states died." *Id.*

Plaintiffs in this litigation "are individuals who [allegedly] suffered death, injury, or distress as a direct and proximate result of being administered one or more NECC Contaminated Drugs compounded, sold and distributed by the NECC and [certain affiliated defendants] and administered by a defendant healthcare provider." ECF No. 1719 ¶ 17. Tennessee Clinic Defendants are nine of the "defendant healthcare provider[s]." *See* ECF No. 1775 at 1. More than one hundred of the actions joined in this litigation are actions in which one or more of the Tennessee Clinic Defendants is a defendant. Ex. A ¶ 15.

FDA is not a party to this litigation. Tennessee Clinic Defendants allege, however, that FDA and its personnel "owed a duty to the Plaintiffs as well as their health care providers to ensure that [MPA] manufactured, sold, and distributed by NECC was sterile and safe for its intended use pursuant to the Federal Food, Drug, and Cosmetic Act." ECF No 1455 at 79 ¶ 36;

[3] A table of docket entries cited in this memorandum appears at p.iii, *supra.*

[4] References to exhibits are to the exhibits to this motion. A table of exhibits appears at p.iv, *supra.*

ECF No. 1456 at 77 ¶ 36. Tennessee Clinic Defendants further allege that "FDA breached its [alleged] duty, proximately causing all injuries and damages alleged." ECF No. 1455 at 79 ¶ 39; ECF No. 1456 at 77 ¶ 39. Based on those allegations, Tennessee Clinic Defendants assert "comparative fault" against FDA and its personnel.[5] ECF No. 1455 at 79 ¶ 36; ECF No. 1456 at 77 ¶ 36.

B. The Subpoena

The Subpoena calls for FDA to produce one or more persons pursuant to Fed. R. Civ. P. 30(b)(6) to testify at deposition about 19 topics under the following six headings: "FDA's authority to investigate, inspect, regulate, and take action against NECC"[6]; "FDA's investigation, inspections, regulation, and actions related to NECC"[7]; "State of Massachusetts"[8]; "The

[5] FDA disputes that any basis exists for any assertion of liability against itself or any of its personnel.

[6] The following topics are listed under this heading:

> 1. The FDA's authority to investigate, inspect, regulate, and take enforcement action against NECC from 2002 through the meningitis outbreak, particularly in light of the information FDA learned about NECC's operations beginning in 2002.
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> 2. The FDA's application of Compliance Policy Guide § 460.200 (2002) when making the decision whether to regulate compounding pharmacies like NECC (*i.e.*, compounding pharmacies with large-scale operations similar to conventional drug manufacturers), both before the meningitis outbreak and since the meningitis outbreak.
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> 3. The FDA's internal policies (written or otherwise), procedures (written or otherwise), and training of staff from 2002 to the time of the meningitis outbreak on the (1) inspection of compounding pharmacies, (2) when regulatory action was appropriate against compounding pharmacies, and (3) distinguishing between traditional compounding, large-scale compounding similar to drug manufacturing (now called "outsourcing facilities"), and conventional drug manufacturers.
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> 4. Generally, FDA's authority to take enforcement actions against drug manufacturers, and how that authority can be exercised (*i.e.*, generally, the differences between the types of enforcement actions available to the FDA, *e.g.*, private censures, warning letters, seizures, injunctions, criminal actions, civil penalties, *etc.*).
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> 5. The decision by FDA to, following the meningitis outbreak, inspect and take action against 30+ compounding pharmacies.

ECF No. 1775-2 at 10.

[7] The following topics are listed under this heading:

> 6. All complaints about NECC known by the FDA prior to the meningitis outbreak and the FDA's response to these complaints, including the internal decision-making regarding whether and how

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information known by the FDA and whether/how it was made public"[9]; "FDA's investigation and inspection of, and action against NECC, following the meningitis outbreak"[10]; and

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to investigate, inspect, and take action against NECC. The complaints and related investigations, inspections, and actions that the witness should be prepared to testify regarding include, but are not limited to: (a) Investigation in March 2002 and subsequent inspection on April 16, 2002 (and related 483); (b) Investigation in October 2002 and subsequent inspection (483 issued February 10, 2003); (c) 2002-03 internal meetings at FDA related to FDA's role in regulating NECC, as described in the February 24, 2003, FDA internal memorandum; (d) The inspection request to the Investigations Branch of the New England District Office of the FDA dated June 2, 2004; (e) The investigation and inspection conducted in September 2004 related to NECC production of trypan blue; (f) Complaints about NECC in January and February 2006; (g) The 2006 Warning Letter issued to NECC (including the findings underlying the letter); (h) June 2007 MedWatch reports to FDA about NECC related to re-packaging of Avastin; (i) June 2008 complaints to the FDA related to NECC betamethasone; (j) September 16, 2008, FDA assignment for inspection of NECC, and the failure to do the inspection; (k) October 31, 2008, letter to NECC asserting that FDA has the authority to take action and that FDA will re-inspect NECC; (l) Reports from anonymous informants in October 2009 and July 2010 about Ameridose and its leadership (leadership shared with NECC) forging sterility documents and knowingly not following proper sterility procedures; (m) 2011 reports from the Colorado Board of Pharmacy and the FDA's failure to act against NECC based on these reports.

7. Any and all complaints about NECC made to the FDA or actions by the FDA in response to complaints about NECC not specifically referenced in Number 6(a)-(m).

8. Any and all correspondence and communications between the FDA and NECC (including its owners, agents, employees, and representatives) not specifically referenced in Number 6(a)-(m)

9. Any and all correspondence and communications between the FDA and state pharmacy boards related to NECC not referenced in Number 6(a)-(m).

10. Whether, (1) based on information learned by the FDA about NECC prior to the meningitis outbreak and (2) considering the statutory factors set out in 503A and the factors set out in the 2002 CPG, NECC was operating like a conventional drug manufacturer (or, at a minimum, operating on a scale not akin to a traditional compounder), subjecting it to FDA regulatory authority.

11. The FDA's authority prior to the meningitis outbreak to share the information FDA had about NECC with the State of Massachusetts and recommend to the State that it take enforcement action against NECC's state license.

ECF No. 1775-2 at 11-12 (formatting modified; footnotes omitted).

[8] The following topics are listed under this heading:

12. The FDA's cooperation with the State of Massachusetts in investigating, inspecting, and taking action against NECC prior to the meningitis outbreak.

13. Whether the FDA believes it was the State of Massachusetts' responsibility to take enforcement action against NECC given the information known by the FDA and the State of Massachusetts about NECC prior to the meningitis outbreak.

ECF No. 1775-2 at 13.

[9] The following topics are listed under this heading:

14. What, if any, of the information known by the FDA about NECC's failure to follow federal law, state law, or industry standards for production of drugs was made publicly available prior to

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"Documents."[11] ECF No. 1775-2 at 10-14. No date for the production of witnesses under the Subpoena is pending. *See* ECF No. 1778 at 2.

C. The Criminal Investigation

In October 2012, the U.S. Attorney's Office for the District of Massachusetts (USAO) commenced a criminal investigation of NECC in response to the same outbreak of fungal meningitis allegedly giving rise to the civil actions joined in this litigation. Ex. A ¶ 4. Led by a team of Assistant U.S. Attorneys (AUSAs) from the USAO and attorneys from the Department of Justice, Civil Division, Consumer Protection Branch, "[t]he NECC criminal investigation is one of the highest priorities of the USAO" and "one of the most significant federal prosecutions currently ongoing in the United States." *Id.* ¶ 5. "The investigation is being conducted by the [FDA] Office of Criminal Investigations ('FDA-OCI'); the Federal Bureau of Investigation; the

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the meningitis outbreak and the steps necessary for potential customers of NECC to obtain the information from the FDA.

15. What information known by the FDA about NECC's failure to follow federal law, state law, or industry standards for production of drugs was available to potential customers of NECC had they requested such information from the FDA prior to the meningitis outbreak.

16. Whether the FDA issued any alerts to health care providers prior to the meningitis outbreaks related to NECC (*e.g.*, that it was unsafe to purchase from NECC; that it was unsafe to purchase certain drugs from NECC; that NECC was operating in violation of federal or state law; *etc.*).

ECF No. 1775-2 at 13.

[10] The following topics are listed under this heading:

17. The findings of the FDA based on its investigation and inspection of NECC following the meningitis outbreak.

18. The source of the information contained in the NECC customer lists published by the FDA following the outbreak.

ECF No. 1775-2 at 13-14.

[11] The following topic is listed under this heading:

19. The documents that the witness(es) is requested to produce in the *duces tecum* attached as exhibit 1 to this Notice.

ECF No. 1775-2 at 14,

Department of Veterans Affairs, Office of Inspector General; the Department of Defense, Defense Criminal Investigative Service; and the United States Postal Inspection Service." *Id.*

In the course of the investigation, agents of FDA-OCI executed search warrants at the site where NECC formerly conducted business and seized, pursuant to those warrants, "more than 760,000 pages of documents from NECC"; "electronic media containing NECC's email, financial, and operational records"; and "numerous physical items," including "compounded drugs in bulk form; compounded drugs in vials, syringes, bottles, and bags; drug ingredients; lab materials; lab equipment; packaging materials; and surveillance videos." Ex. A ¶ 6. "AUSAs and law enforcement agents [also] conducted a thorough review of NECC's regulatory history, including its previous inspections by the FDA and the Massachusetts Board of Registration in Pharmacy, and NECC's representations about its business to regulators throughout its years of operation."[12] *Id.* ¶ 7.

D. *Cadden*

Cadden was commenced on December 16, 2014, when a federal grand jury sitting in Massachusetts returned a 131-count indictment against 14 individuals alleged to have been owners, directors, officers, supervisors, or employees of NECC or of Medical Sales Management, Inc., a corporation allegedly sharing ownership with NECC. Ex. B ¶¶ 2-16. None of the defendants in *Cadden* is a party to this litigation. *See* ECF No. 1719 ¶ 8.

Six of the defendants in *Cadden* are charged with having violated 18 U.S.C. § 1962(c) by "conduct[ing] and participat[ing], directly and indirectly, in the conduct of the affairs of [NECC], through a pattern of racketeering activity."[13] Ex. B ¶ 38. The "[r]acketeering [a]cts" with which

[12] NECC filed a petition for reorganization under Chapter 11 of the Bankruptcy Code in December 2012. ECF No. 1811 at 1.

[13] Section 1962(c) provides:

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two of the defendants are charged include murders in the second degree of 25 of the individuals who are alleged to have died after receiving injections of MPA "made and sold by NECC." *Id.* ¶¶ 40, 56-62. If convicted, those defendants face a maximum punishment of life imprisonment. Ex. A ¶ 9.

Five of the defendants in *Cadden* are charged with having violated 18 U.S.C. § 371 by conspiring among themselves and with "other persons known and unknown to the Grand Jury" to "defraud the United States * * * of and concerning its right to have its business and its affairs, and particularly the transaction of the official business of [FDA], conducted honestly and impartially, free from corruption, fraud, improper and undue influence, dishonesty, unlawful impairment, and obstruction."[14] Ex. B ¶ 77. The "[m]anner and [m]eans" of the alleged conspiracy are alleged to have included the defendants' ostensible operation of NECC "as a state-regulated pharmacy, dispensing drugs pursuant to valid, patient-specific prescriptions as required by Massachusetts law, rather than as a drug manufacturer distributing drugs in bulk to customers without prescriptions and thereby subject to heightened regulatory oversight by the FDA." *Id.* ¶ 78. The "overt acts" committed by the defendants "[i]n furtherance of the [alleged] conspiracy and to effect [its] objects" are alleged to include the following:

> 89. On or about May 20, 2003, in response to an FDA inspection of NECC, defendant (1) CADDEN wrote to the FDA, "we are not subject to (nor are we voluntarily subjecting ourselves to) current good manufacturing practices

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> It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

[14] Subject to an exception dealing with penalties, § 371 provides:

> If two or more persons conspire to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.

> (cGMPs) as promulgated by the FDA, since we are a compounding pharmacy, not a manufacturer."
>
> 90. On or about October 1, 2004, in response to an FDA inspection of NECC, defendant (9) GREG CONIGLIARO falsely wrote to the FDA, NECC "compounds numerous different sterile and non-sterile preparations to fill patient-specific, physician prescriptions." Defendant (9) GREG CONIGLIARO further falsely noted, "[w]e always compound only the amount we anticipate will be required based on our prescribing physician's historical prescribing patterns." Defendant (9) GREG CONIGLIARO concluded by stating, "we are a small-scale, family-run, compounding-only pharmacy, not a manufacturer. As such, we are not subject to GMP."
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> 91. On or about January 5, 2007, in response to an FDA Warning Letter issued to NECC, defendant (1) CADDEN falsely wrote to the FDA, "NECC dispenses compounded medications upon the receipt of valid prescriptions. We are engaged in the practice of pharmacy and comply with the Massachusetts Board of Registration in Pharmacy's laws and rules." With respect to an allegation that NECC had informed its customers to provide names of staff members instead of patients, defendant (1) CADDEN falsely wrote, "[t]his allegation contradicts all of our standard operating procedures."

Id. ¶¶ 88-91.

The 14 defendants in *Cadden* were arraigned on December 17, 2014. Ex. A ¶ 9. "Since that date, the USAO has provided the defense with approximately 8.7 million pages of discovery." *Id.* "No trial date is presently set." *Id.* "The prosecution team is actively engaged in extensive pretrial proceedings, including interviewing new witnesses, continuing to review and assess seized documents and other evidence, preparing and producing discovery to the criminal defendants, and responding to filings in the criminal case." *Id.* "The USAO anticipates calling multiple FDA witnesses at trial." *Id.*

ARGUMENT

FDA SHOULD NOT BE REQUIRED TO PRODUCE ANY WITNESS FOR DEPOSITION UNDER THE SUBPOENA UNTIL 30 DAYS AFTER THE COMPLETION OF TRIAL IN *CADDEN* OR THE ENTRY OF GUILTY PLEAS BY ALL DEFENDANTS IN THAT ACTION.

"The decision whether or not to stay civil litigation in deference to parallel criminal proceedings is discretionary." *Microfinancial, Inc. v. Premier Holidays Int'l, Inc.*, 385 F.3d 72, 77 (1st Cir. 2004). Although "[a] movant must carry a heavy burden to succeed in such an endeavor," *id.*, this Court on multiple occasions has stayed civil litigation in deference to parallel criminal proceedings on the government's motion. *See, e.g., In re TelexFree Sec. Litig.*, No. 4:14-md-02566-TSH, MDL Case Mgt. Order No. 5 ¶ 2 (D. Mass. Mar. 10, 2015) (Ex. C hereto) & *SEC v. TelexFree, Inc.*, 52 F. Supp. 3d 349, 354 (D. Mass. 2014) (staying multidistrict litigation and civil enforcement action involving alleged pyramid and Ponzi scheme pending resolution of parallel criminal proceedings); *Zavatsky v. O'Brien*, 902 F. Supp. 2d 135, 149 (D. Mass. 2012) (staying discovery in action under 42 U.S.C. § 1983 alleging employment discrimination on the basis of political affiliation "while the ongoing criminal investigation and state civil proceedings develop").

The decision to stay civil litigation in deference to parallel criminal proceedings "involves competing interests." *Microfinancial*, 385 F.3d at 78. "Balancing these interests is a situation-specific task, and an inquiring court must take a careful look at the idiosyncratic circumstances of the case before it." *Id.* Though "each instance is sui generis," the following factors "typically bear on the decisional calculus":

> (i) the interests of the civil plaintiff in proceeding expeditiously with the civil litigation, including the avoidance of any prejudice to the plaintiff should a delay transpire; (ii) the hardship to the defendant, including the burden placed upon him should the cases go forward in tandem; (iii) the convenience of both the civil and criminal courts; (iv) the interests of third parties; * * * (v) the public interest[;]

> * * * * (vi) the good faith of the litigants (or the absence of it) and (vii) the status of the cases."

Id. In addition to the factors listed in *Microfinancial*, "another factor that courts consider is the extent to which the issues in the criminal case overlap with those presented in the civil case." *SEC v. TelexFree*, 52 F. Supp. 3d at 352; *see SEC v. Nicholas*, 569 F. Supp. 2d 1065, 1070 (C.D. Cal. 2008) (holding that the extent of overlap is "'the most important factor [in ruling on a motion to stay]'") (court's brackets) (quoting Milton Pollack, *Parallel Civil & Criminal Proceedings*, 129 F.R.D. 201, 203 (1989)); *In re Adelphia Commc'ns Sec. Lit.*, 2003 WL 22358819, at *3 (E.D. Pa. May 13, 2003) (holding that "[t]he similarity of the issues is considered the most important threshold issue in determining whether or not to grant a stay").

> In weighing the factors relevant to a particular case,
>
> the *public interest* in the criminal case is entitled to precedence over the civil litigant: "a trial judge should give substantial weight to [the public interest in law enforcement] in balancing the policy against the right of a civil litigant to a reasonably prompt determination of his civil claims or liabilities."

In re Ivan F. Boesky Sec. Litig., 128 F.R.D. 47, 49 (S.D.N.Y. 1989) (court's emphasis and brackets) (quoting *Campbell v. Eastland*, 307 F.2d 478, 487 (5th Cir. 1989)). As to the other factors that may be relevant, "a concern for judicial efficiency does not necessarily militate against the granting of a stay," *In re Worldcom, Inc. Sec. Litig.*, 2002 WL 31729501, at *8 (S.D.N.Y. Dec. 5, 2002), and "courts may insist that the plaintiff establish more prejudice than simply a delay in his right to expeditiously pursue his claim." *Adelphia*, 2003 WL 22358819, at *4. The plaintiff may thus be required to demonstrate "a particularly unique injury, such as the dissipation of assets or an attempt to gain unfair advantage from the stay." *Id.*

In this case, the public interest militates strongly in favor of the issuance of a protective order providing that FDA shall not be required to produce any witness for deposition under the

Subpoena until 30 days after the completion of trial in *Cadden* or the entry of guilty pleas by all defendants in that action. The outbreak of fungal meningitis at the heart of *Cadden* affected 751 patients in 20 states, killing 64 of them. Ex. A ¶ 4. Two of the defendants in *Cadden* face "potential punishments of life imprisonment for their actions." *Id.* ¶ 13. *Cadden*, accordingly, "is one of the most significant federal prosecutions ongoing in the United States." *Id.* ¶ 5. For these reasons, this litigation is one in which "the *public interest* in the criminal case is entitled to precedence over the civil litigant[s]," s*ee Boesky*, 128 F.R.D. at 49, and one, in particular, in which "[t]he public deserves a criminal prosecution of the defendants unaffected by civil litigation focused on identical events." Ex. A ¶ 13. *See also SEC v. TelexFree*, 52 F. Supp. 3d at 353 (holding that "the public interest in unimpeded criminal law enforcement outweighs the civil interests here").

The commonality of issues also weighs strongly in favor of a stay of the depositions. The testimony sought by the Subpoena "relates to some, if not much, of the same conduct at issue in the criminal prosecution, that is, the FDA's authority, inspection history, and post-outbreak inspection and investigation of NECC." Ex. A ¶ 14. Compliance with the Subpoena "could involve depositions of more than one FDA witness, given the broad topics and subject areas for which a deponent is sought, and these depositions would be given on behalf of the FDA." *Id.* By themselves, these circumstances make a stay of the depositions appropriate. *See SEC v. TelexFree*, 52 F.3d at 352 (stay entered where "the substance of the two parallel actions [was] nearly identical"); *Nicholas*, 569 F. Supp. at 1070 (stay entered where "the high degree of overlap and interrelatedness of the cases meant that "dual litigation [did] not serve the interests of efficiency or judicial economy"); *WorldCom*, 2002 WL 31729501, at *4 (stay entered as to certain of the defendants where "[t]he facts alleged with respect [to those defendants] in the

Consolidated Complaint [were] essentially identical with those alleged with respect to them in the Indictment and the Information").

A stay of the depositions under the Subpoena would also protect the integrity of the *Cadden* prosecution. If any deposition under the Subpoena were to be taken prior to the trial in *Cadden*, the testimony of the witness "would be available for use in the criminal matter as prior statements or admissions" and "would also prematurely and broadly disclose essential elements of the government's case-in-chief, allowing the criminal defendants to tailor defenses to fit the anticipated proof." Ex. A ¶ 14. The testimony also "might reveal information about the FDA-OCI agents' investigatory actions and potentially could lead to identification of non-FDA witnesses or informants who provided investigative leads or other information to the agents." *Id.* ¶ 16. "Disclosure of the identities of these individuals" might prompt "additional deposition and discovery request in this civil proceeding, which might well, in turn, provide the criminal defendants with sworn statements by non-FDA government witnesses and prematurely disclose essential elements of the government's case-in-chief." *Id.* Premature disclosure of those elements ought not to be required. *Cf., e.g., SEC v. Beacon Hill Asset Mgmt.*, 2003 WL 554618, at *2 (S.D.N.Y. Feb. 27, 2003) (entering stay of "[d]epositions, interrogatories, requests for admission, and any other discovery that would create statements of any person whom the United States Attorney for the District of New Jersey certifies may be called as a witness before the grand jury or in any ensuing criminal proceeding"); *WorldCom*, 2002 WL 31729501, at *10 (stay entered where "[t]he Government represent[ed] that the usefulness of its cooperating witnesses [would] be impaired if they [were] subjected to depositions or required to answer interrogatories before the completion of the criminal proceedings"); *SEC v. Downe*, 1993 WL 22126, at *13 (S.D.N.Y. Jan. 26, 1993) (holding that, "where a party or witness in a civil case is cooperating

with a grand jury investigation relating to the subject matter of the civil suit, there is a compelling reason to stay discovery of the civil case pending resolution of the criminal investigation").

Staying the depositions under the Subpoena until after the trial in *Cadden* would also protect the prosecution team from undue burden. If the depositions are permitted to go forward prior to trial, "the USAO's prosecution team [will] need to be involved in preparing the FDA deposition witness(es)," both to ensure that "the team is aware of and understands the details of the witness(es)' testimony and how the testimony would relate to presentation of the government's case in the criminal proceeding" and to ensure "the completeness and accuracy of each witness's testimony, thereby reducing the appearance of inconsistencies from one proceeding to the next." Ex. A ¶ 14. The need for "the USAO's prosecution team * * * to be involved in preparing the FDA deposition witnesses" would have two "burdensome effects on the criminal prosecution." *Id.* First, "[i]t would interfere with the prosecution team's work in the criminal case, including interviewing new witnesses, reviewing seized documents and evidence, preparing and producing discovery, and conducting pretrial litigation, at a crucial stage of the case." *Id.* Second, "[i]t would also force the USAO now, months before the criminal trial, to prepare its trial strategy in the criminal case and the role and expected testimony of FDA witnesses in that strategic plan." *Id.* Because of "the strong public interest" in the "effective enforcement" of the law "through criminal proceedings," the USAO should not be forced to take any steps that would impair that effective enforcement. *See WorldCom*, 2002 WL 31729501, at *10.

Finally, staying the depositions under the Subpoena until after the trial in *Cadden* would protect the rights of the 14 defendants in that action. Any deposition under the Subpoena taken

prior to the trial "could generate substantial pretrial publicity" that "could affect the ability to seat a fair and impartial jury," thereby "affect[ing] the rights of [those] defendants to a fair trial." Ex. A ¶ 15. In theory, a protective order could be used to shield any testimony obtained under the Subpoena from unauthorized disclosure but any such order could have but limited efficacy where, as here, "[t]he fungal meningitis outbreak was an unprecedented public health crisis"; "the USAO's criminal investigation has generated substantial coverage in both national and local media for more than two years;" and the testimony would be subject to use in more than 680 civil actions. *Id.* 15.

By contrast, staying the depositions under the Subpoena until after the trial in *Cadden* could "produce some efficiencies in these civil cases." Ex. A ¶ 17. Much of the testimony for which the Subpoena calls "will be elicited in the criminal case during the government's case-in-chief" through the testimony of the "multiple FDA witnesses" whom "the USAO anticipates calling." *Id.* That testimony may persuade the Tennessee Clinic Defendants that "they no longer need a deposition from the FDA at all, or instead may need only a more limited deposition focusing on a narrower set of topics." *Id. See, e.g., In re Grand Jury Proceedings (Williams),* 995 F.2d 1013, 1018 n.11 (11th Cir. 1993) (holding that stays of civil proceedings may "prove useful," in spite of the delays they cause, "as the criminal process may determine and narrow the remaining civil issues"); *WorldCom*, 2002 WL 31729501, at *8 (holding that "'a stay in the action will streamline later civil discovery since transcripts from the criminal case will be available to the civil parties'") (quoting *Rosenthal v. Giuliani*, 2001 WL 121944, at *2 (S.D.N.Y. Feb. 9, 2001)); *Brock v. Tolkow*, 109 F.R.D. 116, 120 (E.D.N.Y. 1985) (holding that "the resolution of the criminal case might reduce the scope of discovery in the civil case or otherwise simplify the issues").

It has long been established that "the power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants" and that, "[e]specially in cases of extraordinary public moment, the individual may be required to submit to delay not immoderate in extent and not oppressive in its consequences if the public welfare or convenience will thereby be promoted." *Landis v. N. Am. Co.*, 299 U.S. 248, 254, 256 (1936) (Cardozo, J.). *Cadden* is a "case[] of extraordinary public moment" because of the number of deaths and serious injuries caused by the drugs made and distributed by NECC and also because of the seriousness of the charges against the defendants. This Court should therefore issue a protective order providing that FDA shall not be required to produce any witness for deposition under the Subpoena until after the completion of the criminal proceedings.

CONCLUSION

For the foregoing reasons, FDA's motion for protective order should be granted and Tennessee Clinic Defendants' motion to compel should be denied.

Respectfully Submitted,

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